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10/596,237	06/05/2006	Karin Golz-Berner	101215-228	3867

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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,237	GOLZ-BERNER ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24,26,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24, 26, 30, and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 6/4/2010 and 6/25/2010 have been entered.

Claims 17-24, 26, 30, and 31 are pending and under consideration herein.

Withdrawn Claim Rejections

The rejection of claim 18 under 35 U.S.C. 112, second paragraph as being vague and indefinite is withdrawn in light of Applicant's amendments to the claims filed 6/4/2010.

The rejection of claims 17, 20, 23, 24, 30, and 31 under 35 U.S.C. 103(a) as being unpatentable over Stora as evidenced by Critical Care Medicine Tutorials is withdrawn in light of Applicants' amendments to the claims.

The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Stora as evidenced by Critical Care Medicine Tutorials and further in view of Gross et al. '318 is withdrawn in light of Applicants' amendments to the claims.

The rejection of claims 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Stora as evidenced by Critical Care Medicine Tutorials and further in view of Gross et al. '601 is withdrawn in light of Applicants' amendments to the claims.

The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Stora as evidenced by Critical Care Medicine Tutorials and further in view of Pelle et al. and Nakanishi et al. is withdrawn in light of Applicants' amendments to the claims.

The rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Stora as evidenced by Critical Care Medicine Tutorials and further in view of Lu is withdrawn in light of Applicants' amendments to the claims.

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 23, 24, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109, patented Jun. 2002) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999).

Regarding claims 17, 20, 23, and 24, Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.95% Silicone DC®345, a silicone polymer; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system as in instant claims 17 and 24. As to claim 30, Examples 3 and 4 teach a presence of 55.12% by weight of Silicone DC®345 (a silicone polymer). As to claim 31, Stora teaches topically applicable emulsions with controlled refractive indices and viscosity values. Therefore, these emulsions are formed as topically applicable lotions, creams, or gels (see column 2, lines 3-48).

Stora does not specify the partial pressure of the oxygen gas in the formulation disclosed. However, Zastrow et al. teach cosmetic and dermatological formulations comprising phospholipids and fluorocarbons which together form lamellar aggregates which are loaded with oxygen, preferably up to the saturation limit. A preferred partial pressure is in the range of 10 to 40 mPa (80 to 300 mm Hg) (see column 1, lines 35 and 36; column 2, lines 25-28; column 3, lines 29-30 and lines 45-50). Similarly, Zastrow et al. teaches that perfluorinated or highly fluorinated hydrocarbon compounds are

included because these compounds are desirably capable of transporting gases such as oxygen (see column 2, lines 58-61).

Regarding claim 17, the embodiments of the invention of Stora do not illustrate a formulation having an oxygen carrier system necessarily having a presence between 6 and 10% by mass of the total formulation. However, Zastrow suggests that the aggregates (oxygen carrier system) comprising the fluorocarbon and oxygen are present in a quantity of at least 2.5 wt % based on the total composition and preferably in the range of 10-50 wt% (see column 2, lines 20 and 29-30). This range of oxygen carrier system as taught by Zastrow et al. overlaps with the instantly recited range. Additionally, it would have been within the skill of the artisan to dilute the base formulation presented above prior to application in order to optimize the formulation's efficacy and minimize cost.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to load oxygen in the fluorocarbon carrier as taught by Zastrow in the fluorocarbon carriers in the formulations of Stora. One would have been motivated to do so since Zastrow et al. teaches that a preferred oxygen pressure is up to the saturation limit, a value in the range of 80 to 300 mmHg, a range which includes the data points of the instantly recited range and where Zastrow specifies that higher oxygen content is desirable.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) as

applied to claims 17, 20, 23, 24, 30, and 31, and further in view of Gross et al. (US 5,637,318, (hereinafter, the '318 reference), patented Jun. 1997).

The teachings of Stora and Zastrow et al. are delineated above. As to claim 18, the functional limitation of oxygen content inherently would lie within the range of 25-40% upon loading according to the instant specification. For example, page 2 of the instant specification (paragraph 5) describes the oxygen loading in which oxygen gas within a broad range of partial pressures is bubbled through the carrier system with stirring at ambient temperature for a specified time period. Upon bubbling oxygen through the carrier composition as described, the oxygen presence necessarily would result in an oxygen quantity equal to or approximating the quantity instantly claimed.

Stora do not teach a quantitative value for oxygen loading in a perfluorinated hydrocarbon carrier as in the instant claim.

Gross et al. ('318) teach oxygen-laden fluorocarbons and fluorocarbon mixtures suitable for dermatological use (see abstract, in particular). Additionally, Gross et al. state that fluorocarbons are capable of transporting oxygen (see '318 reference, column 2, line 39) and with the aid of known oxygen gas solubilities, the vapor pressure (an inherent property), and the critical solubility temperature, the loading of fluorocarbons with oxygen can be adjusted by the skilled artisan (see '318 reference, column 4, lines 21-26).

Therefore, regarding claim 18, it would have been prima facie obvious to one of ordinary skill in the art to adjust the presence of oxygen in a fluorocarbon carrier for a dermatological application as suggested by Gross et al. in order to improve the oxygen

carrying capacity of a topically applicable composition such as the one taught by Stora. One would have been motivated to do so in order to optimize the benefits associated with oxygen delivery to the skin as evaluated according to the final product. Since this optimization process would have been routine procedure, one of ordinary skill in the art at the time the invention was made would have expected resulting success.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) as applied to claims 17, 20, 23, 24, 30, and 31, and further in view of Gross et al. (US 5,643,601, (hereinafter, the '601 reference), patented Jul. 1997).

As to claim 22, Stora teach that the perfuming ingredients can belong to a variety of chemical classes including alcohols, esters, acetates, terpenic hydrocarbons, and essential oils of natural or synthetic origin (see column 5, lines 54-60).

Regarding claim 21, Stora does not expressly include a gelling or thickening agent in the carrier system. As to claim 22, Stora does not limit the carrier system oil base to one which is a vegetable oil, an ester, or a mixture thereof.

However, Gross et al. ('601) teach phospholipid-and fluorocarbon containing cosmetics to be formulated as gels, creams, lotions, etc. in order to supply adequate oxygen to the skin upon application (see abstract, in particular). Gross et al. teach that the fluorocarbons in this composition analogous to that of Stora can be selected for oxygen gas solubility, partial vapor pressure, and lipid solubility according to the specific intended application ('601 reference, see column 3, lines 28-30).

Specifically, Gross names perfluorodecalin as a rapid release oxygen carrier which also is embodied in the invention (see '601 reference, column 3, line 34; see also, column 4, Table 1). As to claim 21, Gross et al. teach the inclusion of hydroxyethyl cellulose (a thickening agent), in a gel mask formulation of the invention (see '601 reference, column 7, example 9). As to claim 22, Gross et al. teach jojoba oil and liquid paraffin as components in Example 5, a body lotion. One of ordinary skill in the art at the time of the invention would have recognized that jojoba oil is a liquid wax produced in the seed of the jojoba plant and is a mixture of wax esters desirably present in cosmetic and topical applications.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stora and Gross et al. in order to maintain the benefits of the fluorocarbon formulation component (i.e., optimized oxygen incorporation and delivery) and to further optimize this oxygen carrier component in the analogous product resulting from this combination of teachings. The skilled artisan would have been motivated to optimize physical properties such as formulation thickness and therefore manageability by including a known gelling agent such as hydroxyethyl cellulose as is routine in the cosmetic arts and as is suggested in the disclosure of Gross et al., particularly since Gross et al. state a variety of cosmetically acceptable formulations such as gels, pastes, ointments, creams, lotions, etc (see '601 reference, column 4, lines 10-11). Similarly, the skilled artisan would have been motivated to implement jojoba oil into the topically applicable formulations on account of its commonly recognized and desirable properties such as being odorless

and relatively shelf-stable when compared with other vegetable oils useful as cosmetic carriers, as taught by Gross et al.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) and Gross et al. (US 5,643,601) as applied above and further in view of Pelle et al. (US 5, 811,083, patented Sep. 1998), and Nakanishi et al. (US 6,576,623 B1, patented Jun. 2003).

The teachings of Stora, Zastrow, and Gross are delineated above. Stora does not disclose the inclusion of tocopherol or a tocopherol derivative in the instantly prescribed quantity. It is noted that Gross et al. teach the inclusion of antioxidants such as a- tocopherol (see '601 reference, column 3, lines 66-67) in analogous perfluorodecalin-containing cosmetic compositions.

However, these references do not teach the instantly specified tocopherol derivatives in the instantly specified quantity. Nakanishi et al. teach silicone compounds useful in cosmetic applications wherein tocopheryl succinate is taught as a functional equivalent to a-tocopherol (see column 10, lines 58-60), and Pelle et al. specifically teach tocopherol derivatives for use in cosmetic compositions. Specifically, Pelle et al. disclose advantages of using tocopherol derivatives for regulating skin aging and other disorders and suggest a most preferred quantity of 0.01 to 1.0 wt. % for topical applications (see column 7, lines 32-36). Further, one of ordinary skill would have been motivated to optimize this formulation component presence in order to impart desired

properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedures as quoted above.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute tocopheryl succinate as taught by Nakanishi for the a-tocopherol disclosed in the formulations of Gross et al. One would have been motivated to do so since these a-tocopherol and tocopheryl succinate have been shown in the prior art to be interchangeable and to have insubstantial differences both structurally and functionally. Likewise, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Pelle et al. with the teachings of Gross et al. in order to determine a desirable quantity of tocopherol derivative in a cosmetic formulation. Also, it would have been prima facie obvious to combine the teachings of Gross et al. and Stora and to utilize Gross' suggestion to include tocopherol or its derivative in a topically applicable perfluorodecalin-containing cosmetic composition. One would have been motivated to combine these teachings since Gross et al. teaches the advantage of avoiding auto-oxidation processes in other formulation components by adding an anti-oxidant such as alpha-tocopherol to a formulation analogous to that of Stora. Since Gross et al. does not specify an acceptable quantity, the skilled artisan would have been motivated to look to Pelle et al. in order to determine a topically acceptable quantity of the tocopherol agent.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) as

applied to claims as applied to claims 17, 20, 23, 24, 30, and 31 above and further in view of Lu (US 2003/0235548 A1, filed Jun. 2002).

The teachings of Stora and Zastrow are delineated above. As to claim 26, these references do not teach an embodiment of the invention in which a silicone oil is present in a quantity between 6 and 35% by mass of the total formulation.

However, Lu teaches cosmetic formulations structured with silicone polymers wherein the formulations include a liquid fatty phase comprising at least one silicone oil. Specifically, the liquid fatty phase advantageously contains at least 30% by weight of silicone oil(s). Although Lu does not teach the exact limitation as in the instant claim, Lu teaches a premise from which the skilled artisan would have been inclined to optimize. Lu teaches a range of silicone oil overlapping with the range instantly claimed. See MPEP 2144.05 regarding the patentability of overlapping ranges.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the quantity of silicone oil as taught by Lu in the formulations of Stora. One would have been motivated to do so since Lu teaches that the silicone polymers used in the invention are more soluble in low-viscosity silicone oils (see page 5, paragraph [0074]).

Response to Arguments

Applicant's arguments presented 6/4/2010 have been fully considered but are moot in light of amendment. As noted above, all rejections previously presented and

not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Regarding the rejection over the Stora reference, Applicant argues that there is no suggestion in the Stora reference to provide for a precise, limited range of perfluorinated hydrocarbon (see first full paragraph, page 2 of Remarks). This argument is not persuasive since Stora teaches perfluorodecaline in a quantity of 2.23% in Example 1, and this quantity is included in the instantly recited range. See MPEP 2131.02. Regarding Applicant's assertion that the instant invention is limited such that a perfluorinated hydrocarbon oxygen carrier is present at no greater than 1%, it is noted that this limitation is not in the claims. The relevance of the Stora reference is therefore maintained.

Regarding the rejections of claim 18, 21, and 22, Applicant presents that it is surprising that loading of oxygen by way of a fluorinated hydrocarbon system preserves the retention of oxygen over time. Applicant references the previously submitted Declaration to support arguments that a silicone polymer acts synergistically with the perfluorinated hydrocarbon to achieve the oxygen retention. To the extent that this is an argument of unobviousness due to unexpected results it is unpersuasive. MPEP 716.02(b) indicates that evidence relied on to support assertions of unexpected results should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance". In this case, there is no statistical analysis of the data in the declaration, so the results relied on to support the assertion are not of statistical significance. Thus Applicant has failed to meet the burden of

establishing that the results are significant. In the absence of appropriate evidentiary support, the assertion that the oxygen loading characteristics of the claimed compositions are "surprising" is merely the expression of attorney opinion, and is unpersuasive. Note also that the newly cited Zastrow reference supports the use of perfluorinated or highly fluorinated hydrocarbon compounds to transport gases such as oxygen at the instantly recited partial pressures.

Regarding the rejection of claim 19, Applicant takes the position that the Pelle reference does not cure the alleged deficiency of the Stora/Gross combination since the cited reference do not add the tocopherol derivative to the instantly claimed system for the same reason (improved stability) as presented by Applicant. Applicant then concludes that there is no suggestion or motivation in the Pelle reference to add tocopherol derivatives to a composition of Stora. In reply, the relevance of the cited references is maintained, and Applicant's arguments are not persuasive. See MPEP 2144 (IV) which permits rationale different from Applicant's. Applicant also asserts that the claim is limited to specific tocopherol derivatives. It is noted that this limitation is addressed by Nakanishi in combination with Pelle and the other cited references.

Regarding the rejection of claim 26 over Stora in view of Lu, Applicant concludes that Lu does not cure the aforementioned alleged deficiencies of the Stora reference. In reply, this position is not persuasive because any deficiencies of the Stora reference that are not addressed by the Lu reference are cured by the Zastrow reference, as set forth in detail in the rejections above.

Conclusion

No claims are found allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635